

## **REMARKS**

### **I. Introduction**

By the present Amendment, claims 1, 2, 4, 8, 9, and 10 have been amended. No claims have been added or cancelled. Accordingly, claims 1-13 remain pending in the application. Claims 1, 4, 8, and 10 are independent.

### **II. Office Action Summary**

In the Office Action of May 26, 2009, claims 4-7 and 11-13 were objected to under 37 CFR §1.75(c) as being of improper form. Claims 1-13 were rejected under 35 USC §112, second paragraph, as being indefinite. Claims 2 and 4 were rejected under 35 USC §101 as reciting a use without setting forth any steps involved in the process. Claims 4-8 and 11-13 were rejected under 35 USC §103(a) as being unpatentable over U.S. Patent Application No. 2002/0138003 to Bukshpan in view of U.S. Patent No. 6,176,842 issued to Tachibana et al. ("Tachibana"). Claims 2, 3, 9, and 10 were rejected under 35 USC §103(a) as being unpatentable over Bukshpan in view of Tachibana, and further in view of U.S. Patent No. 5,305,745 issued to Zacouto. These rejections are respectfully traversed.

### **III. Objections**

Claims 4-7 and 11-13 were objected to under 37 CFR §1.75(c) as being of improper form because they depend from multiple dependent claims 3 and 10.

By the present Amendment, Applicants have amended claims 4 and 10, in part, to eliminate the multiple dependency. Withdrawal of this objection is therefore respectfully requested.

**IV. Rejections under 35 USC §112**

Claims 1-13 were rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Regarding this rejection, the Office Action indicates that claims 1, 2, 4, and 8 recite the language "and/or" which renders the claim indefinite because it is unclear whether the limitation is following the phrase or part of the claimed invention.

By the present Amendment, Applicants have amended the claims to eliminate all instances of the phrase and/or. Withdrawal of this rejection is therefore respectfully requested.

**V. Rejections under 35 USC §101**

Claims 2 and 4 were rejected under 35 USC §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process. Regarding this rejection, the Office Action indicates that the claims provide for the use of living body light, but do not set forth any steps in the method/process, thereby resulting in an improper definition of a process.

By the present Amendment, Applicants have amended the claims to either eliminate or clarify this language. Applicants further note that these claims are actually apparatus claims, and did not intend to claim a process.

Withdrawal of this rejection is therefore respectfully requested.

**VI. Rejections under 35 USC §103**

Claims 1, 4-8 and 11-13 were rejected under 35 USC §103(a) as being unpatentable over Bukshpan in view of Tachibana. Regarding this rejection, the Office Action alleges that Bukshpan discloses a method for diagnosing and treating a thrombus that includes introducing an ultrasound contrast agent into a human body, and transmitting the ultrasound signal into the body. The Office Action further alleges that Bukshpan discloses a method for lysing a thrombus in a human body, including introducing an ultrasound contrast agent, transmitting an ultrasound signal towards the thrombus at least one transmission frequency, and receiving an ultrasound reflected off of the thrombus, with the ultrasound signal having a temporal characteristic. The Office Action further indicates that Bukshpan discloses calculating a spatial location of thrombus from the temporal characteristic, and transmitting ultrasound energy toward the spatial location.

Regarding the apparatus claims, the Office Action alleges that Bukshpan discloses an apparatus for treating a thrombus in a human body that includes a sheet of material placeable on the human body, a plurality of ultrasound transmitters for transmitting ultrasound signals into the human body, with the transmitters being fixedly located within the sheet and oriented within the sheet such that the transmission is effected into the human body. The Office Action further alleges that the apparatus includes a plurality of ultrasound receivers for receiving ultrasound signals reflected from the human body, the receivers being fixedly located within the sheet and oriented such that the reception is effected from the human body, a layer of ultrasound coupling medium applied to a surface of the ultrasound transmitters and the ultrasound receivers, the layer being conformable to a contour of the human

body, and a processor for processing the received signals, the processor being functional to calculate a temporal characteristic of the received signals and diagnose a thrombus from the calculated temporal characteristics.

The Office Action admits that Bukshpan fails to disclose a light source to irradiate the living body and a light receiving unit. Tachibana is relied upon for disclosing delivery of ultrasonic energy to a light activated drug, contrast agent, or thrombolytic agent that is injected to a patient for therapeutic functions such as treating thrombosis. The Office Action further indicates that Tachibana discloses transmitting ultrasound waves or energy to penetrate the tissue site, a light source such as a fiber optic to direct light to a targeted tissue which includes the light activated drug, and activation of the drugs within the tissue by exposure to the light. The Office Action concludes that it would have been obvious to combine the light detection unit of Tachibana to the device of Bukshpan in order to arrive at the claimed invention. Applicants respectfully disagree.

By the present Amendment, Applicants have amended the claims to better define the invention and clarify the features that are not shown or suggested by the art of record. As amended, independent claim 1 defines a thrombus detecting apparatus that comprises:

- a transducer, which is attached to a monitor portion of a subject and transmits and receives ultrasonic waves, a transmitter and receiver unit, which transmits and applies driving pulses to the transducer and receives echo signals output from the transducer, and

- a detector making use of ultrasonic waves, which processes output signals of the transmitter and receiver unit and detects a thrombus passing through a blood vessel, and

- a light source, which generates living body inspection light,

a probe, which is attached to a monitor portion of the subject and irradiates the living body inspection light from the light source to the subject,

a light receiving unit, which receives living body inspection light irradiated from the probe and passed through the subject and outputs electrical signals depending on the intensity of the received living body inspection light, and

a detector making use of living body light, which processes the output signals of the light receiving unit and detects a thrombus passing through a blood vessel,

characterized in further comprising a thrombus comprising a thrombus counting unit, which counts the number of thrombus by combining thrombus detected by the detector making use of ultrasonic waves and thrombus detected by the detector making use of living body light.

The thrombus detecting apparatus of independent claim 1 includes a transducer that is attached to a monitor portion of a subject and transmits and receives ultrasonic waves. A transmitter and receiver unit are provided to transmit and apply driving pulses to the transducer and receive echo signals output from the transducer. A detector capable of utilizing the ultrasonic waves processes the output signals of the transmitter and receiver unit, and detects a thrombus passing through the blood vessel. The apparatus further includes a light source which generates living body inspection light, a probe which is attached to a monitor portion of the subject and irradiates the living body inspection light from the light source to the subject, a light receiving unit which receives living body inspection light irradiated from the probe and passed through the subject and outputs signals depending on the intensity of the received living body inspection light, and a detector which processes output signals of the transmitter and receiver unit and detects a thrombus passing through the blood vessel. According to independent claim 1, a thrombus counting unit is provided to count the number of thrombus by combining the results

of the detector using the ultrasonic waves and the detector using the living body light.

As discussed in the Specification, detection sensitivity using ultrasonic waves differs from that which uses living body light. For example, when using living body light, the measurement depth is approximately 20mm. Accordingly, living body light is suitable when measuring blood vessels at shallow portions of the body. When measuring blood vessels in deep portions of the body, however, the use of ultrasonic waves is preferred due to its ability to measure at depths of 20mm to 240mm. By simultaneously using living body light and ultrasonic waves, it is possible to accurately detect and measure thrombus throughout the entire range simultaneously. See paragraphs [0038] and [0039] of the published application.

The Office Action alleges that the combination of Bukshpan and Tachibana discloses all the features recited in independent claim 1. This does not appear to be the case. Bukshpan discloses a method for ultrasonic coronary thrombolysis wherein an intravenous injection of a thrombus-specific ultrasound contrast agent is performed, and an array of ultrasonic transducers transmits ultrasound signals to the patient. The reflected signals are then analyzed in order to determine the ratio of the second harmonic to the first harmonic components of the signals. A high ratio indicates the presence of a thrombus, and a time-of-flight data for each of the receivers is used to calculate the spatial location of the thrombus. As admitted in the Office Action, Bukshpan fails to provide any disclosure or suggestion for using living body light. Rather, only ultrasonic signals are utilized. Applicants further note that Bukshpan appears to only discuss detection and calculation of the position of thrombus using ultrasonic coronary thrombolysis.

Tachibana discloses an ultrasound assembly that can be used with light activated drugs to cause tissue death within a tissue site. The assembly can be provided in the form of a kit that includes a media with a light activated drug that is activatable upon exposure to a particular level of ultrasound energy. A catheter is also provided for delivering the light activated drug to the tissue site. An ultrasound transducer is configured to transmit the necessary level of ultrasound energy to penetrate the tissue site and activate the light activated drug. Contrary to the present invention, Tachibana does not use ultrasound waves together with living body light. Rather, Tachibana appears to only disclose the use of ultrasound waves. While a light activated drug is disclosed, Tachibana explicitly indicates that the ultrasound transducer is utilized to provide the requisite amount of energy to activate the drug. The cited references simply fail to provide any disclosure or suggestion for features now recited in independent claim 1, such as:

- ...a transmitter and receiver unit, which transmits and applies driving pulses to the transducer and receives echo signals output from the transducer, and

- a detector making use of ultrasonic waves, which processes output signals of the transmitter and receiver unit and detects a thrombus passing through a blood vessel, and

- a light source, which generates living body inspection light,

- a probe, which is attached to a monitor portion of the subject and irradiates the living body inspection light from the light source to the subject,

- a light receiving unit, which receives living body inspection light irradiated from the probe and passed through the subject and outputs electrical signals depending on the intensity of the received living body inspection light, and

- a detector making use of living body light, which processes the output signals of the light receiving unit and detects a thrombus passing through a blood vessel,

- characterized in further comprising a thrombus comprising a thrombus counting unit, which counts the number of thrombus by

combining thrombus detected by the detector making use of ultrasonic waves and thrombus detected by the detector making use of living body light.

It is therefore respectfully submitted that independent claim 1 is allowable over the art of record.

Claims 2 and 3 depend from independent claim 1, and are therefore believed allowable for at least the reasons set forth above with respect to independent claim 1. In addition, these claims each introduce novel elements that independently render them patentable over the art of record.

As amended, independent claim 4 defines a thrombus treating apparatus that comprises:

- a transducer, which is attached to a monitor portion of a subject and transmits and receives ultrasonic waves,

- a transmitter and receiver unit, which transmits and applies driving pulses to the transducer and receives echo signals output from the transducer, and

- a detector making use of ultrasonic waves, which processes output signals of the transmitter and receiver unit and detects a thrombus passing through a blood vessel, and

- a light source, which generates living body inspection light,

- a probe, which is attached to a monitor portion of the subject and irradiates the living body inspection light from the light source to the subject,

- a light receiving unit, which receives living body inspection light irradiated from the probe and passed through the subject and outputs electrical signals depending on the intensity of the received living body inspection light,

- a detector making use of living body light, which processes the output signals of the light receiving unit and detects a thrombus passing through a blood vessel,

- characterized in further comprising a thrombus counting unit, which counts the number of thrombus which by combining thrombus detected by the detector making use of ultrasonic waves and thrombus detected by the detector making use of living body light, and



a treatment use ultrasonic wave generating device, which transmits ultrasonic waves for dissolving a thrombus flowing through the blood vessel based on the counted number of the thrombus.

The thrombus treating apparatus of independent claim 4 now recites various features that are similar to those recited in independent claim 1. For example, a transducer is attached to a monitor portion of a subject to transmit and receive ultrasonic waves. Additionally, a light source is attached to a monitor portion of the subject to irradiate living body inspection light to the subject. As previously discussed with respect to independent claim 1, the cited references failed to provide any disclosure or suggestion for combining the use of ultrasonic waves and living body light.

It is therefore respectfully submitted that independent claim 4 is allowable over the art of record.

Claims 5-7 depend from independent claim 4, and are therefore believed allowable for at least the reasons set forth above with respect to independent claim 4. In addition, these claims each introduce novel elements that independently render them patentable over the art of record.

As amended, independent claim 8 defines a thrombus detecting method that comprises:

- a step of transmitting and irradiating ultrasonic waves and living body inspection light from an ultrasonic wave transducer and a living body light measurement probe attached at a monitor portion of a subject toward a blood vessel at the monitor portion,

- a step of measuring echo signals and/or penetrating living body light from the blood vessel at the monitor portion, and

- a step of counting a number of thrombus flowing in the blood vessel at the monitor portion based on a combination of the intensity of the measured echo signals and penetrating living body light.

According to the method of independent claim 8, ultrasonic waves and living body inspection light are respectively transmitted and irradiated from an ultrasonic wave transducer and a living body light measurement probe attached at a monitor portion of a subject toward a blood vessel and the monitor portion. Echo signals and penetrating living body light from the blood vessel are measured at the monitor portion. The number of thrombus flowing in the blood vessel at the monitor portion is counted based on a combination of the intensity of the measured echo signals and penetrating living body light. Thus, according to independent claim 8, both ultrasonic waves and living body inspection light are utilized in order to detect the number of thrombus flowing in the blood vessel. As previously discussed, the cited references fail to provide any disclosure or suggestion for utilizing both ultrasonic waves and living body light.

It is therefore respectfully submitted that independent claim 8 is allowable over the art of record.

Claim 9 depends from independent claim 8, and is therefore believed allowable for at least the reasons set forth above with respect to independent claim 8. In addition, this claim introduces novel elements that independently render it patentable over the art of record.

As amended, independent claim 10 defines a thrombus treating method that comprises:

- a step of transmitting and irradiating ultrasonic waves and living body inspection light from an ultrasonic wave transducer and a living body light measurement probe attached at a monitor portion of a subject toward a blood vessel at the monitor portion,

- a step of measuring echo signals and penetrating living body light from the blood vessel at the monitor portion,

a step of counting a number of thrombus flowing in the blood vessel at the monitor portion based on a combination of the intensity of the measured echo signals and penetrating living body light, and

a step of transmitting treatment use ultrasonic waves toward the blood vessel from the treatment use transducer attached to the subject for dissolving a thrombus passing through the blood vessel when a thrombus is counted in the counting step.

Similar to independent claim 8, independent claim 10 transmits and irradiates both ultrasonic waves and living body inspection light from an ultrasonic wave transducer and a living body light measurement probe. Additionally, the number of thrombus flowing in the blood vessel at the monitor portion is counted based on a combination of the intensity of the measured echo signals and penetrating living body light. As previously discussed, the cited references fail to utilize both ultrasonic waves and living body light.

It is therefore respectfully submitted that independent claim 10 is allowable over the art of record.

Claims 11-13 depend from independent claim 10, and are therefore believed allowable for at least the reasons set forth above with respect to independent claim 10. In addition, these claims each introduce novel elements that independently render them patentable over the art of record.

Claims 2, 3, 9, and 10 were rejected under 35 USC §103(a) as being unpatentable over Bukshpan in view of Tachibana, and further in view of Zacouto. Regarding this rejection, the Office Action indicates that the combination of Bukshpan and Tachibana discloses all the features of the claims except for an alarm device to generate an alarm based on a detection result, and a portable self power source. Zacouto is relied upon for disclosing an external alarm that can be activated

based upon detection of images of blood corpuscles or cells that are abnormal in shape, content, localization, or number.

As previously discussed, Applicants have amended claim 10 to be in independent form, and incorporate features not shown by the combination of Bukshpan and Tachibana, such as the use of both ultrasonic waves and living body light. Applicants' review of Zacouto has failed to reveal any disclosure or suggestion for the features that are lacking in Bukshpan and Tachibana. Consequently, the inclusion of Zacouto as a tertiary reference still fails to render the claimed invention obvious.

It is therefore respectfully submitted that claims 2, 3, 9, and 10 are allowable over the art of record.

## **VII. Conclusion**


For the reasons stated above, it is respectfully submitted that all of the pending claims are now in condition for allowance. Therefore, the issuance of a Notice of Allowance is believed in order, and courteously solicited.

If the Examiner believes that there are any matters which can be resolved by way of either a personal or telephone interview, the Examiner is invited to contact Applicants' undersigned attorney at the number indicated below.

**AUTHORIZATION**

Applicants request any shortage or excess in fees in connection with the filing of this paper, including extension of time fees, and for which no other form of payment is offered, be charged or credited to Deposit Account No. 01-2135 (Case: 983.46144X00).

Respectfully submitted,  
ANTONELLI, TERRY, STOUT & KRAUS, LLP.

/Leonid D. Thenor/   
Leonid D. Thenor  
Registration No. 39,397

LDT/vvr  
1300 N. Seventeenth Street  
Suite 1800  
Arlington, Virginia 22209  
Tel: 703-312-6600  
Fax: 703-312-6666

Dated: August 26, 2009